Amendments to the Claims

A complete list of all the presently or formerly pending claims in the application is provided below, with suitable headings to show the status of each claim and, where appropriate, its current text.

Claim 1 (Original). A fast dissolving and taste masked sildenafil solid dosage form comprising:

(i) sildenafil granules which granules comprise at least 45% by weight of a salt of sildenafil, a solubilisation inhibitor for said salt of sildenafil and optionally a sweetening agent and

(ii) one or more disintegrants wherein the disintegrants or combination of disintegrants are present in the form of agglomerates having an average agglomerated particle size of at least 50um, said agglomerates comprising at least 10% by weight of disintegrant.

Claim 2 (Original). A fast disintegrating solid dosage form as claimed Claim 1 in which the sildenafil granules comprise at least 55% by weight of a salt of sildenafil.

Claim 3 (Original). A fast disintegrating solid dosage form as claimed in Claim 2 in which the sildenafil granules comprise at least 65% by weight of a salt of sildenafil.

Claim 4 (Currently Amended). A fast disintegrating solid dosage form as claimed in **Claim 1** ~~**any preceding claim**~~ in which the salt of sildenafil is selected from hydrochloride, hydrobromide, sulphate or bisulphate, phosphate or hydrogen phosphate, acetate, citrate, fumarate, gluconate, lactate, maleat, succinate and tartrate.

Claim 5 (Currently Amended). A fast disintegrating solid dosage form as claimed in **Claim 1** ~~**any preceding claim**~~ in which the solubilisation inhibitor increases the pH when the sildenafil granules are dissolved in aqueous medium.

Claim 6 (Original). A fast disintegrating solid dosage form as claimed in Claim 5 in which the solubilisation inhibitor is selected from sodium hydroxide, sodium carbonate, sodium bicarbonate, sodium phosphate, sodium citrate, calcium oxide, calcium carbonate, magnesium oxide and magnesium carbonate.

Claim 7 (Currently Amended). A fast disintegrating solid dosage form as claimed in **Claim 1** ~~**any preceding claim**~~ in which the solubilisation inhibitor releases the counter ion of the sildenafil salt.

Claim 8 (Currently Amended). A fast disintegrating solid dosage form as claimed in **Claim 1** ~~**any preceding claim**~~ in which the solubilisation inhibitor increases the hydrophobicity of the tablet.

Claim 9 (Original). A fast disintegrating solid dosage form as claimed in Claim 8 in which the solubilisation inhibitor is selected from glyceryl monostearate, waxes and sodium stearyl lactate.

Claim 10 (Currently Amended). A fast disintegrating solid dosage form as claimed in **Claim 1** ~~**any preceding claim**~~ in which the salt of sildenafil is present in an amount to provide from 5 to 150mg/solid dosage form of sildenafil.

Claim 11 (Original). A fast disintegrating solid dosage form as claimed in Claim 10 in which the salt of sildenafil is present in an amount to provide from 5 to1 00mg/solid dosage form of sildenafil.

Claim 12 (Currently Amended). A fast disintegrating solid dosage form as claimed in **Claim 1** ~~**any preceding claim**~~ in which the agglomerates comprise at least 25% by weight of disintegrant.

Claim 13 (Original). A fast disintegrating solid dosage form as claimed in Claim 12 in which the agglomerates comprise from 25 to 100% by weight of disintegrant.

Claim 14 (Currently Amended). A fast disintegrating solid dosage form as claimed in **Claim 1** ~~any preceding claim~~ in which at least 50% of the disintegrant is present in the tablet is in the form of said agglomerates.

Claim 15 (Original). A fast disintegrating solid dosage form as claimed in Claim 14 in which at least 75% by weight of the disintegrant is present in the form of said agglomerates.

Claim 16 (Original). A fast disintegrating solid dosage form as claimed in Claim 15 in which at least 90% by weight of the disintegrant is present in the form of said agglomerates.

Claim 17 (Original). A fast disintegrating solid dosage form as claimed in Claim 16 in which all of the disintegrant in the tablet is present in the form of agglomerates.

Claim 18 (Currently Amended). A fast disintegrating solid dosage form as claimed in **Claim 1** ~~any preceding claim~~ in which the average particle size of the agglomerates is in the range 75 to 500 μm.

Claim 19 (Currently Amended). A fast disintegrating solid dosage form as claimed in **Claim 1** ~~any preceding claim~~ in which the tablet comprises at least 2% by weight of disintegrant.

Claim 20 (Original). A fast disintegrating solid dosage form as claimed in Claim 19 in which the tablet comprises from 4 to 20% by weight of disintegrant.

Claim 21 (Currently Amended). A fast disintegrating solid dosage form as claimed in **Claim 1** ~~any preceding claim~~ in which the disintegrant is selected from croscarmellose cellulose, crospovidone and sodium starch glycollate.

Claim 22 (Currently Amended). A fast disintegrating solid dosage form as claimed in **Claim 1** ~~**any preceding claim**~~ in which the tablet additionally comprises water-soluble fillers or diluents selected from lactose, sucrose, dextrose and mannitol.

Claim 23 (Original). A method of making a fast disintegrating solid dosage form comprising the steps of:

(i) forming granules comprising at least 45% by weight of a salt of sildenafil, a solubilisation inhibitor for said salt of sildenafal and optionally a sweetening agent,

(ii) forming agglomerates having an average agglomerated particle size of at least 50μm and comprising one or more disintegrants such that the agglomerates comprise at least 10% by weight disintegrant,

(iii) mixing the agglomerates from step (ii) with the granules of steps (i) and optionally other tableting excipients, and

(iv) compressing the mixture from step (iv) to form a solid dosage form.

Claim 24 (Original). A method of making a fast disintegrating solid dosage form in which the granules are prepared by wet granulation, dry granulation, melt extrusion, extrusion-spheronisation, spray drying, co-spray drying or spray agglomeration.

Claim 25 (Currently Amended). A method as claimed in ~~**Claim 23 or**~~ Claim 24 in which the ~~**ingredients of the mixture which is compressed in step (iv) are as defined in any one of Claims 2 to 22**~~ **granules comprise at least 45% by weight of a salt of sildenafil, a solubilisation inhibitor for said salt of sildenafil and optionally a sweetening agent**.